

ELSI Research and the New NIH Data Management and Sharing (DMS) Policy

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Outline

1. Basics of the DMS Policy
2. Preparing and Submitting a DMS Plan
3. Resources
4. Discussion



Basics of the Data Management and Sharing Policy

NIH Data Management and Sharing (DMS) Policy

To promote the responsible sharing of scientific data

Applies to most research, funded or conducted in whole or in part by NIH, that generates **scientific data**, regardless of data type or funding level

- Plan and budget to manage and share data
- Submit a DMS plan for NIH review when applying for funding
- Comply with the approved DMS plan

Learn more and find sample DMS Plans @
sharing.nih.gov

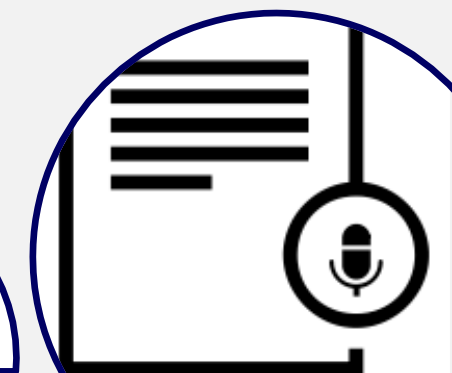
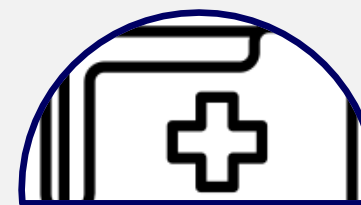
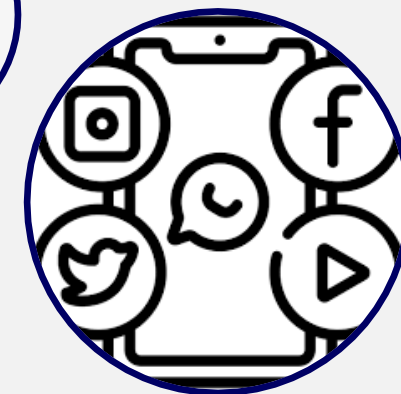
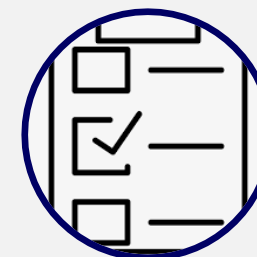
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Scientific Data: The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, **regardless of whether the data are used to support scholarly publications.**



Examples of ELSI scientific data

- Voice recordings
- Raw and coded transcripts from interviews/focus groups, stakeholder meetings, Delphi processes, deliberative events
- Data from social media, websites, public records
- Raw and recoded survey responses
- Outcomes data from interventions
- Ethnographic observations
- Data extracted from source articles in a meta-analysis, scoping review, lit review
- Documents and data arising from materials used in a legal, conceptual or normative analysis
- Data from participants' health care records



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Applies to applications coming in after
January 25, 2023

NIH expects researchers to
maximize sharing of scientific data

What kinds of (ELSI) applications need to comply?

- Most NIH funding mechanisms
- Includes K01s, K99s, R00, R03, R21, R01, U-grants most other research grants
- Does NOT include:
 - T32 and fellowship (e.g., F99, F31) grants
- Administrative supplements are subject to the policies governing the parent award.

Factors to Consider: Model of Access



Sharing through **controlled access** if...

- Explicit limitations on sharing
- Data pose particular risks to participants or groups
- Data cannot be sufficiently de-identified
- Unanticipated risks are discovered after initial planning

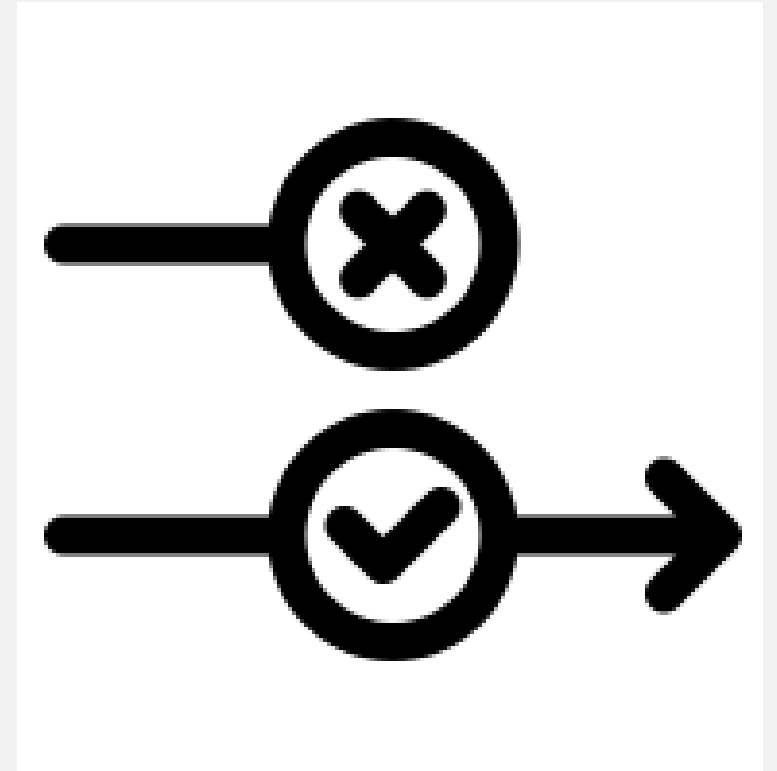


Sharing through **unrestricted access** if....

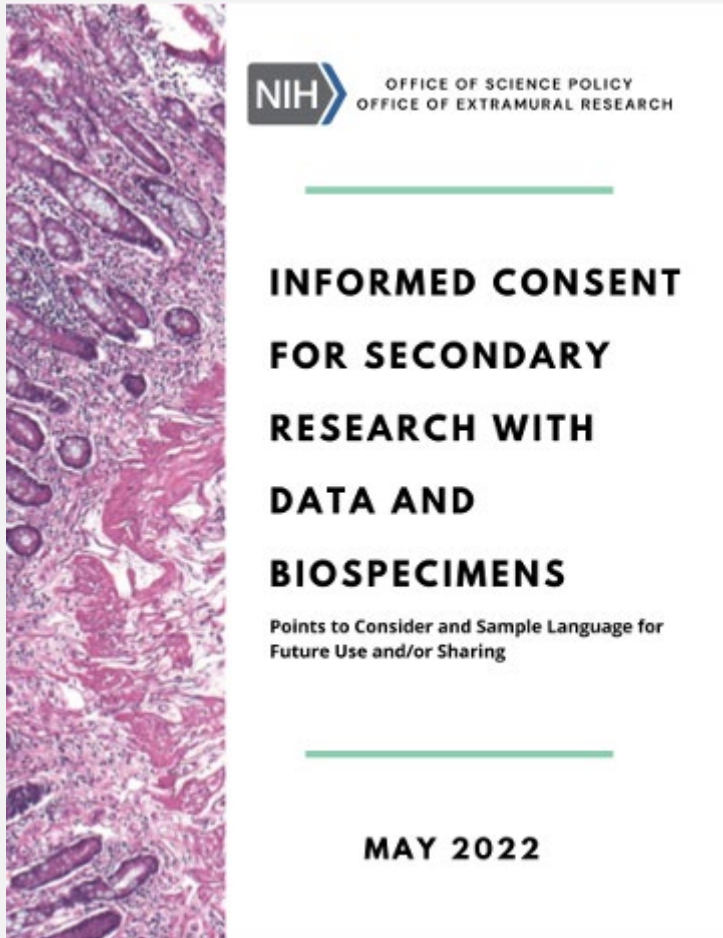
- De-identified
- Institutional review finds unrestricted sharing poses very low risk
- Explicitly consented for an unrestricted model of access

Justifiable limitations on sharing



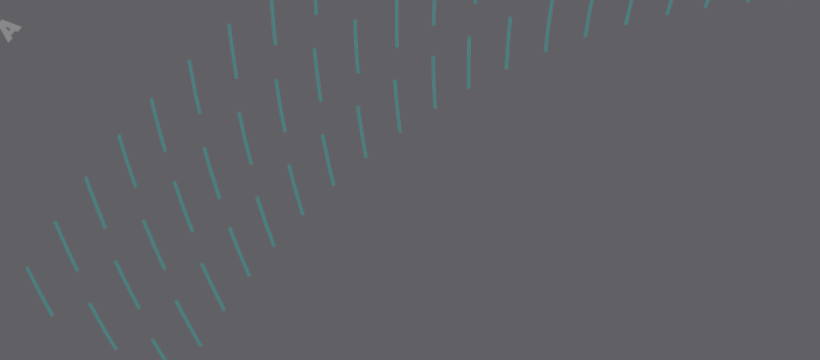
- Consent
- Privacy or safety would be compromised
- Federal, state, local, Tribal law or policy
- Existing or anticipated agreements
- Other technical, ethical, legal factors



Informed Consent

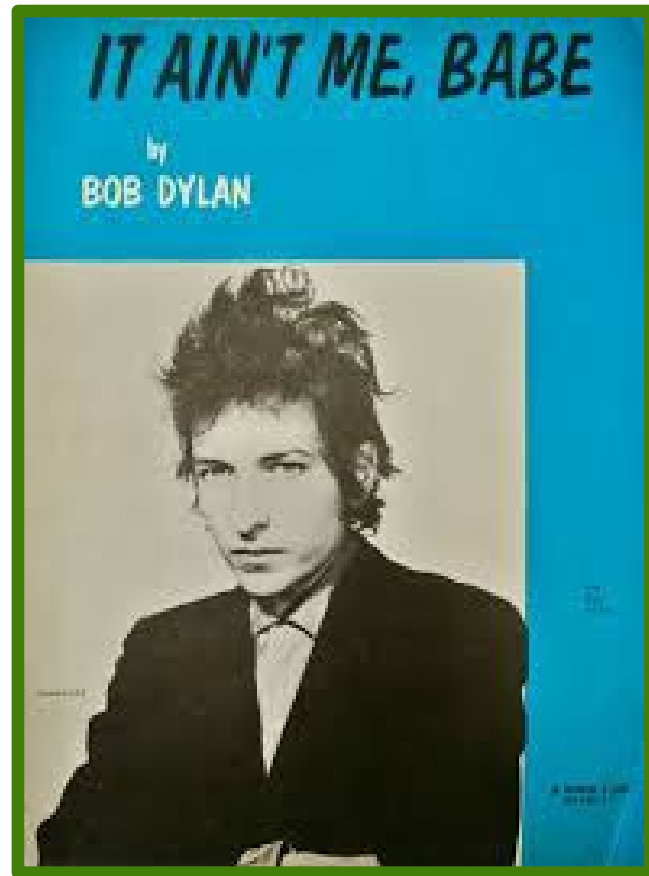


- DMS Policy encourages researchers to plan for how data management and sharing will be addressed
- **NIH Resource provides sample language, which can be adjusted**
- Broad consent not required
 - Researcher and IRB to determine appropriate scope of sharing
- Building respectful partnerships with American Indian/Alaska Native communities



Preparing and submitting a Data Management & Sharing Plan and budget in a grant

No data being collected
or T32 or F-series grant?



Research grant
collecting scientific data?





DMS Plan

The DMS plan and budget will not affect impact score

- The DMS plan won't be seen by peer reviewers
- The budget for data sharing will be available to review but not score-driving

A plan is needed even if you are not sharing data

- Account for all the data being collected

Before Starting the DMS Plan

- Check the funding opportunity
 - Repositories to use
 - Sharing requirements
 - Budget limits or requirements
- Consider preliminary conversations with IRB, communities affected, program officers as needed
- Decide on a repository



Where to Share?



NIH encourages use of the established repository that is most appropriate for your data type and discipline

Repository specified by an NIH Institute or the Funding Notice
NHGRI – [AnVIL](#)

Discipline or data-type specific repository

Other potential options for small less complex data sets

Check specifics of the repository you will use

Unique identifiers

Data and metadata formats

Privacy protection/
de-identification practices

Details about open and
controlled access

Writing the DMS Plan



- 2 pages
- The [template](#) NIH provides is optional but helpful
- [Sample plans](#) are available
- [DMPTool](#)
- No hyperlinks in plan
- Includes genomic data sharing if applicable
- Resource Sharing Plan is separate

Elements of the DMS Plan



1. Data types
2. Related tools, software and code
3. Standards
4. Data preservation, access, timelines
5. Access, distribution, reuse considerations
6. Oversight of data management and sharing

How much detail do I need to provide in the plan?



- Check the NIH Sample Plans for examples
- Address each data type that is being treated differently
- Be clear which data will and will not be shared.
- Clear rationale for anything not shared or limited



Submitting the plan



A new “**Other Plan(s)**” field added to the PHS 398 form to collect a single PDF attachment

Research Plan Section			
5. Vertebrate Animals	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
6. Select Agent Research	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
7. Multiple PD/PI Leadership Plan	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
8. Consortium/Contractual Arrangements	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
9. Letters of Support	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
10. Resource Sharing Plan(s)	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
11. Other Plan(s)	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
12. Authentication of Key Biological and/or Chemical Resources	<input type="text"/>	Add Attachment	Delete Attachment View Attachment

Budgeting for Data Sharing Activities



You may request funds for data management and sharing

Allowable

- Curating, de-identifying data
- Formatting to standards
- Transmission & storage
- Repository deposit fees
- Creating supporting docs, metadata
- Some local infrastructure

Not allowable

- Infrastructure covered by institutional overhead costs
- Routine conduct of research
- Double charged direct and indirect costs


Submitting the budget

Show Amount on R&R Budget Form: line item in section F. Other Direct Costs

F. Other Direct Costs		Funds Requested (\$)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Data Management and Sharing Costs	
9.		
10.		

Justify costs PHS 398 Modular Budget Form: within
Additional Narrative Justification

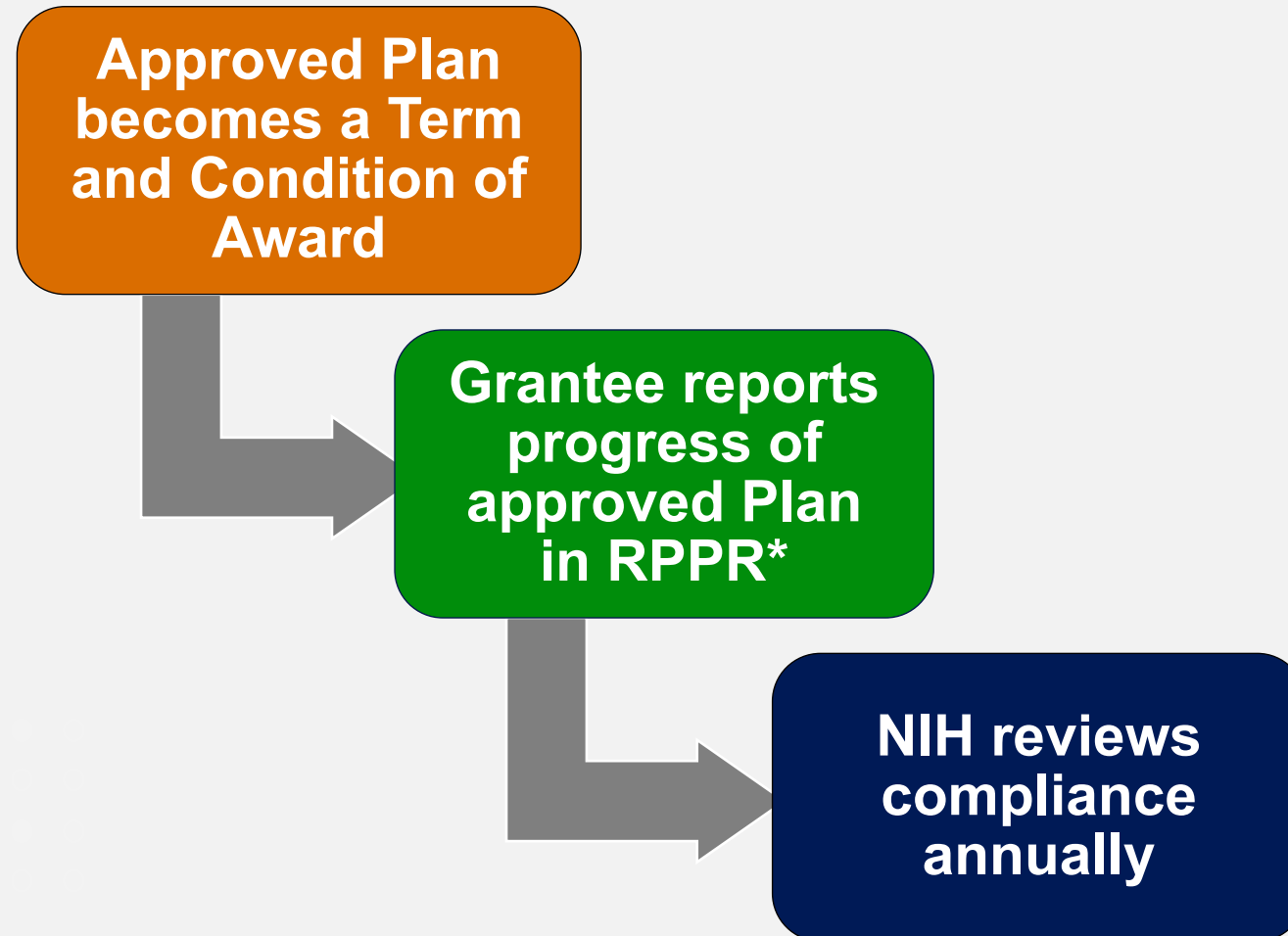
2. Budget Justifications			
Personnel Justification		Add Attachment	Delete Attachment View Attachment
Consortium Justification		Add Attachment	Delete Attachment View Attachment
Additional Narrative Justification		Add Attachment	Delete Attachment View Attachment



**Your plan must be
approved by NIH
prior to award**

Monitoring Compliance

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Communication

- Contact us well in advance of your application to discuss questions
- Make sure your AO knows how to upload the plan
- We will contact you after programmatic review if we are considering the grant for funding.



Resources

How to select a repository and draft a DMS plan

[DMS Plan Format Page](#)

[Budgeting for Data Management & Sharing](#)

[Writing a Data Management & Sharing Plan](#)

[Selecting a Data Repository](#)

[Repositories for Sharing Scientific Data](#)

General websites on data sharing policy and resources

[NIH Sharing Website](#)

[NHGRI Sharing Website](#)

[NIH FAQs](#)

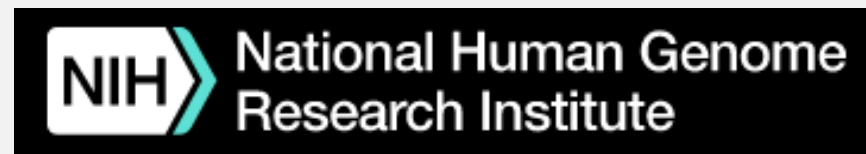
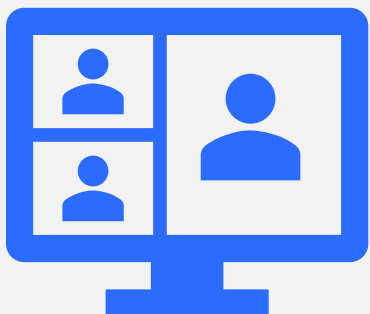
[ELSI FAQs](#)

Associated notices/policies

[Management and Sharing of American Indian/Alaska Native Participant Data](#)

[NIH Notice on Protecting Privacy while Sharing](#)

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Q & A